Interview Summary	Application No.	Applicant(s)	
	09/835,759	BARBERA-GUILLEM, EMILIO	
	Examiner	Art Unit	
	David J Blanchard	1642	

All participants (applicant, applicant's representative, PTO personnel):

(1) *David J Blanchard*. (3)_____.

(2) *Scott Harders*. (4)_____.

Date of Interview: *22 October 2003*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *A telephone call was made to applicant's attorney, Scott Harders on 10/22/2003 to request an election of species. Applicant did not elect telephonically and requested that the restriction requirement be mailed*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

_____
Examiner's signature, if required

DETAILED ACTION

1. It is acknowledged that applicants have elected Group I (claims 1-13) in Paper No. 6 (8/8/2002) with traverse and have further elected the species comprising a monoclonal antibody in Paper No. 8 (6/24/2003), with traverse. A telephone call was made to Scott Harders on 10/22/2003 to request an oral election with respect to Species A (a-f) listed below, but did not result in an election being made. Upon further consideration the restriction requirement in Paper No. 6 and the election of species requirement in Paper No. 8 are vacated and a new restriction requirement follows.

2. Multiple elections are required in this restriction requirement. Applicants are required to elect one of inventions I-VIII. If one of Groups I, III-V, VII or VIII are elected applicant is required to elect one of species A (a-f) and one of species B (g-j) as set forth in item 6 below.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a vaccine comprising an immunotherapeutic composition and a tumor associated antigen, classified in class 424, subclass 184.1.

II. Claims 14-16, drawn to a vaccine comprising micelles of tumor-associated antigen, classified in class 424, subclass 277.1.

III. Claims 17-36, drawn to a method of treatment by administering a vaccine comprising an immunotherapeutic composition and a tumor associated antigen, classified in class 424, subclass 184.1.

IV. Claims 37-42, drawn to a method of treatment by administering a vaccine comprising a tumor associated antigen, classified in class 424, subclass 277.1.

V. Claims 43-50, drawn to a method of making a vaccine comprising an immunotherapeutic composition and a tumor associate antigen, classified in class 424, subclass 184.1.

VI. Claims 51-56, drawn to a method of making a composition comprising a tumor associated antigen, classified in class 424, subclass 277.1.

VII. Claims 57-63, drawn to a method of priming the immune system, classified in class 424, subclass 141.1.

VIII. Claims 64-68, drawn to a kit for priming the immune system, classified in class 424, subclass 141.1 and 277.1.

4. Claims 1 links inventions I, III-V, VII and VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 1. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including

all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I, II and VIII represent separate and distinct products, which are made by materially different methods, which have different modes of operation and different functions. The vaccine of Group I comprises an immunotherapeutic composition and a tumor-associated antigen, the vaccine of Group II comprises micelles of tumor-associated antigens and the vaccination kit of Group VIII comprises an immunotherapeutic composition, an anti-CD4 monoclonal antibody and a tumor-associated antigen. The vaccines of Groups I, II and VII are all structurally and chemically different from each other. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I, II and VIII are patentably distinct.

The methods of Inventions III-VII differ in the method objectives, method steps and parameters and in the reagents used. Invention III recites a method of treatment with the vaccine of claim 1; Invention IV recites a method of treatment by administering a vaccine comprising an immunotherapeutic composition, an anti-CD4 antibody and a

tumor-associated antigen; Invention V recites a method of making a vaccine; Invention VI recites a method of making the composition of claim 14; Invention VII recites a method for priming the immune system of an individual. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, Inventions IIIVII are separate and distinct in having different method objectives, method steps and different endpoints and are patentably distinct.

Inventions of Groups I-II and V-VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products of Groups I-II could be made by a materially different process, such as by combination of whole cancer cells, or incorporation into carriers.

Inventions of Groups I-II and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I-II could be used for a materially different process, such as to treat a lymphoid tumor.

Inventions of Group VIII and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group VIII could be used for a materially different process, such as to detect a disorder.

6. This application contains claims directed to the following patentably distinct species of the claimed invention: If Groups I, III-V, VII and VIII are elected then a species election is required. Applicant is required to elect one of species A (a-f) **and** one of species B (g-j).

Species A
a) CD19
b) CD 20
c) CD21
d) CD 22
e) CDIM
f) Lym-1

Species B
g) lectins
h) monoclonal antibodies
i) peptides
j) aptamers

The molecules disclosed for species a-f and g-j are patentably distinct because each is structurally and functionally distinct. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims

shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (703) 605-1200. The examiner can normally be reached at (703) 605-1200 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, can be reached at (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,
David J. Blanchard
703-605-1200

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600